UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

BOTULINUM TOXIN RESEARCH
ASSOCIATES, INC.

Plaintiffs,

v. Case No.

JOHN/JANE DOE(S),

Defendants.

COMPLAINT & JURY DEMAND

Botulinum Toxin Research Associates, Inc. ("Plaintiff"), for their Complaint against the Defendants, John/Jane Doe(s) ("Defendants"), allege as follows:

PARTIES

1. Botulinum Toxin Research Associates, Inc. ("BTRA") is a Corporation duly formed and existing under the laws of Massachusetts, and has a principal place of business at 1261 Furnace Brook Parkway #24, Quincy, MA 02169.

2. The true name of Defendants is unknown at this time. Upon information and belief, Plaintiff states that information obtained during discovery will lead to the identification of each Defendant's true name and address and will permit Plaintiff to amend this Complaint to state the same.

JURISDICTION & VENUE

3. This action arises out of tort, specifically the tortious interference with a contractual relationship, and the tortious interference with a business relation.

4. This Court has jurisdiction of this claim under, and by virtue of, 28 U.S.C. § 1332. Upon information and belief, the matter in controversy exceeds the sum or value of $75,000.00, exclusive of interest and costs, and is between citizens of different states.

5. On information and belief, personal jurisdiction in this District over each Defendant is proper because such Defendant's acts complained of herein occurred within and/or had substantial effect within this District.

6. Venue is proper under 28 U.S.C. § 1391(b).

GENERAL ALLEGATIONS

7. In the 1980s, Dr. Eric A. Johnson ("Dr. Johnson") was faculty at the University of Wisconsin-Madison, and a player in the development of the botulinum toxin formulation now commonly known as Botox®. That technology was later acquired by Allergan, Inc., a pharmaceutical company.

8. Botox® is among type A1 botulinum toxin injectable products used cosmetically to temporarily remove wrinkles. In 2007, Botox® sales amounted to $1.2 billion dollars. Botox® appears to produce around $2 billion dollars a year in revenues. The worldwide market of Botox® is anticipated to exceed $10 billion dollars during the next 20 years. However, the composition and toxicity of Botox® limit some of its potential uses.

9. In 1996, Dr. Johnson, now an expert in botulinum toxin, developed a different formulation of the botulinum toxin which is the basis of “PurTox.” PurTox is a superior product, and competitor to the product Botox®.

10. PurTox technology is superior to existing botulinum toxin products in several ways. First, it isolates the single protein (one of seven proteins found in Botox®) that is essential in botulinum toxin applications. This allows PurTox to be applied in

higher doses without triggering the body's immune response, and can therefore be used to treat a patient throughout life without losing its effectiveness. Second, this single toxin penetrates tissue faster, increases the absorption of the toxin, and ultimately lengthens the duration of effect. Third, the PurTox technology also includes applications for treatment of dystonias, pain, spasticity, and many other neurological disorders.

11. Botox® enjoys a huge existing market. PurTox has demonstrated superior qualities to Botox® and additional applications. The PurTox project would have been lucrative. Early projections estimated the project would produce hundreds of millions of dollars for the University of Wisconsin alone.

12. Dr. Gary E. Borodic ("Dr. Borodic") is a Boston surgeon and Harvard professor who has excelled in developing therapeutic applications for botulinum toxin products.

13. Dr. Johnson and Dr. Borodic collaborated after 1991 to produce a complementary composition and application technology for PurTox (the "PurTox Technology") which they assigned to Plaintiff, BTRA. BTRA has manufacturing knowledge and owns composition and application patents for PurTox that are complementary to the purified neurotoxin technology, including **U.S. Patent Nos. 5,401,243; 5,298,019; 5,696,077; 6,429,189; 7,270,826; 7,335,367; 7,459,164; 7,491,403; 7,537,773; 7,670,608; 7,691,394; 7,943,152; 8,580,745; 8,691,769; 8,679,486; 8,241,640; 8,192,979; 8,926,991, and foreign counterparts.**

14. Dr. Borodic was involved in the initial development and FDA licensing of applications for this technology for the treatment of dystonia, facial nerve disease, and blepharospasm. Dr. Borodic raised funds very early on to promote the development of

this technology, and the evolution of medicinal formulations, particularly related to the treatment of blepharospasm. Dr. Borodic worked heavily in high dose formulations, facial applications, and with the development of technology for human pain applications.

15. In 2003, BTRA licensed this technology to the Wisconsin Research Alumni Foundation ("WARF"). A true and correct copy of the license agreement entered into between BTRA and WARF is attached hereto as Exhibit A.

16. WARF subsequently licensed the PurTox Technology to Mentor Corporation a/k/a Mentor Worldwide, LLC ("Mentor") for development. A true and correct copy of the license agreement between WARF and Mentor is attached hereto as Exhibit B.

17. WARF presented Exhibit B (2003 license agreement) to BTRA for consideration prior to the license agreement between WARF and Mentor.

18. Reports projected that Mentor would have an FDA approved PurTox product on the market by 2009.

19. Clinical trials for PurTox produced outstanding results during Phases 1 through 3.

20. In 2009, the Johnson & Johnson Corporation purchased Mentor for almost $1.1 billion dollars. Upon information and belief, much of that sale price was paid to obtain the PurTox Technology.

21. Mentor did not obtain FDA approval for PurTox by 2009, as projected.

22. For all new drug applications, the FDA generally requires "comparability protocols" for serial batches, providing the source of any protein based ingredients. These protocols are meant to monitor variations in chemistry, manufacturing, and controls.

These protocols also demonstrate the competency of the manufacturer to produce a consistent product. The PurTox Botulinum Toxin Type A, Purified Neurotoxin (or "drug substance"), used for the Phase I and Phase II clinical studies of the PurTox technology was manufactured at Metabiologics Inc., in Madison, Wisconsin. It was crucial, in order to perform necessary side-by-side analytical comparability studies, to compare drug substance from each phase of the process.

23. Numerous individuals and several different companies were involved in the early Phase I and Phase II process for PurTox, including Johnson & Johnson, Mentor, Metabiologics, WARF, and others.

24. In or around 2012, Dr. Johnson and Dr. Borodic discovered that samples of the drug substance used in the Phase I and Phase II clinical trials for the PurTox Technology (the “Batches”) had disappeared. Dr. Johnson and Dr. Borodic undertook immediate steps to locate the Batches, but were unsuccessful in doing so. No reasonable answers were provided to Dr. Johnson or Dr. Borodic in response to their questions regarding "materials management."

25. All parties involved with the Phase I and Phase II clinical studies knew or should have known the importance of maintaining the Batches in connection with those studies, for both patient safety reasons and to satisfy the serial analytic testing necessary for FDA approval. However, no explanation or accounting was ever provided, and Dr. Johnson and Dr. Borodic could not determine who had allowed or caused the Batches to be lost or destroyed, or how the loss or destruction occurred.

26. The disappearance of these batches created delays, the need for repeated work, and an almost insurmountable obstacle to Mentor obtaining process validation,

consistency in product for human injection, and ensuring FDA approval. Without the Batches, it became very difficult to demonstrate to the FDA that the drug product, as they intended to manufacture it for use on patients, matched the drug product that had been used in the successful clinical trials. Without the Batches, Mentor failed to perform definitive side-by-side comparability studies necessary to obtain FDA approval.

27. The FDA later put the PurTox project on clinical hold because the Batches had, inexplicably, disappeared resulting in the absence of reference material and failure of FDA approval.

28. In 2013, Mentor announced a collaboration with Valeant Pharmaceuticals International Inc. ("Valeant") to distribute a competitor product ("DYSPORT"). This was done without notice to BTRA, and apparently without notice to WARF.

29. BTRA identified a patent infringement issue by Allergan, Inc. during this time and requested cooperation from WARF and Mentor to finance enforcement via corporate transfer. WARF objected. WARF and Johnson & Johnson objected stating that the transfer of patent enforcement claims would "be contrary to the contracts."

30. On April 1, 2014 Mentor terminated its licensing agreement with WARF.

31. Only three weeks after Mentor terminated the PurTox project, Valeant made a hostile bid for Allergan Inc., the maker of Botox.

32. PurTox has yet to receive FDA approval, and no credible chemical manufacturing controls serial analysis has been done after 10 years.

33. An audit was performed by WARF and consultants, including questions prepared in cooperation with Dr. Johnson, but these audit results were not shared by WARF with Dr. Johnson or with BTRA.

COUNT NO. 1 - TORTIOUS INTERFERENCE WITH BUSINESS RELATIONS

34. BTRA repeats and reincorporates herein the allegations set forth in paragraphs 1-33, above.

35. BTRA had an ongoing business relationship with both Mentor and WARF as a function of the BTRA-WARF licensing agreement (Exhibit A) and the WARF-Mentor licensing agreement (Exhibit B). BTRA had a reasonable expectation for probable future business relationships upon FDA approval of the PurTox Technology derived from the research of Dr. Johnson and the clinical studies by Dr. Borodic. BTRA had reasonable anticipation, and expected a financial benefit from, future contemplated business relationships generated around the PurTox technology.

36. Upon information and belief, unknown Defendants had knowledge of these existing and reasonably anticipated business relationships.

37. Upon information and belief, unknown Defendants intentionally interfered with these existing and reasonably anticipated business relationships by improper motive and by improper means.

38. In particular, in failing to preserve the Batches, and/or aiding the destruction of the Batches, and in failing to provide acceptable process validation and chemistry, manufacturing and controls (CMC) results on the drug product to the FDA, unknown Defendants' conduct was improper and BTRA suffered a loss of advantage directly resulting from unknown Defendants' conduct.

39. Upon information and belief, as a direct result of unknown Defendants' improper acts and/or omissions, BTRA suffered a loss of advantage directly resulting from unknown Defendants' conduct.

COUNT NO. 2 - TORTIOUS INTERFERENCE WITH CONTRACTUAL RELATIONSHIP

40. BTRA repeats and reincorporates herein the allegations set forth in paragraphs 1-39, above.

41. BTRA had a binding contract with WARF as a function of the BTRA-WARF licensing agreement (Exhibit A). WARF subsequently licensed and sublicensed the whole collection of BTRA PurTox technology to Mentor in a subsequent contractual relationship (Exhibit B).

42. Upon information and belief, Unknown Defendants had knowledge of these contractual relationships and intentionally induced, persuaded, and/or prevented parties from performing their contractual obligations under these agreements.

43. Upon information and belief, breach of contract occurred as a direct and proximate result of unknown Defendants' actions and/or omissions.

44. Upon information and belief, unknown Defendants had knowledge of their interference.

45. Upon information and belief, said interference was improper in motive or means, constituted actual malice, and was a violation of well-established industry standards.

46. BTRA was harmed and suffered damages as a consequence of unknown Defendants' conduct, acts, and omissions. Unknown Defendants' conduct is the proximate cause of BTRA's injuries. BTRA's injuries are neither speculative nor conjectural.

RELIEF REQUESTED

WHEREFORE, Plaintiff requests that the Court enter judgment against each unknown Defendant as follows:

A. A Judgment finding unknown Defendants tortiously interfered with BTRA's current and future business relationships.

B. A Judgment finding unknown Defendants tortiously interfered with BTRA's contractual relationships.

C. Entry of Judgment that such unknown Defendants shall pay to BTRA actual damages, lost profits, prospective profits, any profits made by unknown Defendants as a result of their malfeasance, cost of mitigation(s), emotional distress damages where available, and nominal damages where necessary.

D. Entry of Judgment that such unknown Defendants shall pay to BTRA attorney fees incurred in dealing with any third parties as a result of unknown Defendants' intentional interference.

E. Entry of Judgment that such unknown Defendants shall pay BTRA's costs.

F. Entry of Judgment that such unknown Defendants shall pay BTRA's reasonable attorney fees.

G. All other relief as justice may require and/or as otherwise deemed just and proper by this Court.

JURY DEMAND

Plaintiff demands a trial by jury on all counts so triable.

Dated this 5th day of May, 2015.

/s/ *Christopher A. Duggan*

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